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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/779,599	01/07/97	GOEDEL	D P0897C2

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18N2/1230

EXAMINER

ULM, J

ART UNIT

PAPER NUMBER

1812

10

DATE MAILED:

12/30/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 10/14/97
- ☒ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire _____ month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 31 - 33 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 31 - 33 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

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1) Claims 31 to 33 are pending in the instant application and have been amended as requested by Applicant in Paper Number 9, filed 14 October of 1997.

2) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) Claims 31 to 33 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which is not described in the instant specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claim invention or to enable one skilled in the art to make and use the claimed invention for those reasons of record in Paper Number 6. The instant claims are directed to a human protein which associates with the cytoplasmic domain of a tumor necrosis factor (TNF) receptor wherein that protein is encoded by a nucleic which is defined therein as a product by process. The production of the claimed protein requires an isolate nucleic acid and the instant specification does not provide an adequate written description of that isolated nucleic acid. The fact that the instant specification discloses a method through which that

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nucleic acid might or might not be isolated is irrelevant to the instant rejection because it is the isolated nucleic acid, not a method of isolating the nucleic acid, which is required to produce and define the claimed protein. *Amgen Inc. v. Chugai Pharmaceuticals Co. Ltd.*, 18 U.S.P.Q. 2d, 1016, held that;

"A gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and describe how to obtain it. See *Oka*, 849 F.2d at 583, 7 USPQ2d at 1171. Conception does not occur unless one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, e.g., encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property. We hold that when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, i.e., until after the gene has been isolated"

The instant specification does not provide "the detailed constitution" of an isolated nucleic acid encoding a human TRAF

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protein or the protein encoded thereby. Applicant is encouraged to review the recent decision in *The Regents of the University of California v. Eli Lilly and Company*, 43 USPQ2d 1398 (CAFC 1997), which is relevant to the instant rejection.

6) Claims 31 to 33 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6.1) These claims are indefinite because the term "about 30 to 50 bases" is vague and indefinite because one can not distinguish between that which is encompassed by this term and that which is excluded. One can not know if an oligonucleotide of 25 bases or 60 bases is or is not encompassed by this term.

6.2) Claims 31 to 33 are vague and indefinite because the instant specification does not identify that material property of combination of properties which is unique to and, therefore, definitive of a TRAF protein for those reasons of record in Paper Number 6.

7) Applicant's arguments filed 14 October of 1997 have been fully considered but they are not persuasive.

8) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

9) Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stephen Walsh, can be reached at (703) 308-2957.

Official papers filed by fax should be directed to (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. § 132 or which otherwise require a signature, may be used by Applicant and should be addressed to [stephen.walsh@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees will not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. § 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official

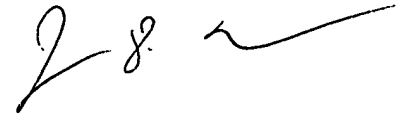
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Gazette of the Patent and Trademark Office on 25 February of 1997
at 1195 OG 89.

Any inquiry of a general nature or relating to the status of
this application should be directed to the Group receptionist
whose telephone number is (703) 308-0196.



JOHN ULM
PRIMARY EXAMINER
GROUP